Sub A3

We claim:

1. A method for determining the presence of cancerous or pre-cancerous cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby expression of MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen expressed on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells; and

(C) diagnosing the presence of significant lesions, when said MN/CA9 antigen is observed on said atypical cells, wherein the significant lesions include adenocarcinoma, invasive carcinoma (CA), or high grade squamous intraepithelial lesions (HSIL);

(D) diagnosing the presence of low grade lesions when said MN/CA9 antigen is absent from said atypical cells but is present on said normal endocervical cells, wherein the low grade lesions include low grade squamous intraepithelial lesions (LSIL) or atypia.

2. The method of claim 1, further comprising:

(E) diagnosing a benign condition when said MN/CA9 antigen is absent from said atypical cells and normal endocervical cells.

3. A method for determining the presence of adenocarcinoma from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby expression of MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen expressed on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells; and

(C) diagnosing the presence of adenocarcinoma, when said MN/CA9 antigen is observed on said atypical cells in a honeycomb configuration.

4. The method of claim 2, wherein said adenocarcinoma is adenocarcinoma *in situ* (AIS) or invasive adenocarcinoma.

5. A method for determining the presence of high grade squamous intraepithelial lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby expression of MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen expressed on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells; and:

(C) diagnosing the presence of high grade squamous intraepithelial lesions (HSIL) when said MN/CA9 antigen is observed on said atypical cells in a tight cluster.

6. A method for determining the presence of significant cancerous or pre-cancerous cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby expression of MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen expressed on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells;

(C) diagnosing the presence of significant lesions, when said MN/CA9 antigen is observed on said atypical cells, wherein the significant lesions include adenocarcinoma, invasive carcinoma, or high grade intraepithelial lesions;

(D) diagnosing the presence of adenocarcinoma, when said MN/CA9 antigen is observed on said atypical cells in a honeycomb configuration; and

(E) diagnosing the presence of high grade squamous intraepithelial lesions (HSIL) when said MN/CA9 antigen is observed on said atypical cells in a tight cluster.

7. A method for determining the presence of low grade cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby expression of MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen expressed on atypical and normal cells of said AGUS cytologically diagnosed Pap smear cells; and

(C) diagnosing the presence of low grade squamous intraepithelial lesions (LSIL) or atypia when said MN/CA9 antigen is absent from said atypical cells but is present on said normal endocervical cells.

8. A method for determining the presence or absence of cancerous or pre-cancerous cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby an MN/CA9 protein or a characterizing fraction thereof, is detected; and

(B) observing the distribution of MN/CA9 antigen expressed on atypical or normal cells of said AGUS cytologically diagnosed Pap smear;

(C) diagnosing the presence of adenocarcinoma, when said MN/CA9 antigen is observed on said atypical cells in a honeycomb configuration;

(D) diagnosing the presence of high grade squamous intraepithelial lesions (HSIL) when said MN/CA9 antigen is observed on said atypical cells in a tight cluster;

(E) diagnosing the presence of low grade squamous intraepithelial lesions (LSIL) and/or atypia when said MN/CA9 antigen is absent from said atypical cells but is present on said normal endocervical cells; and

(F) diagnosing a benign condition when said MN/CA9 antigen is absent from said atypical cells and normal endocervical cells.

9. The method of claim 8, wherein said MN/CA9 antigen comprises a characterizing fraction of an MN/CA9 protein.

10. The method of claim 9, wherein said characterizing fraction of said MN/CA9 protein comprises at least one immunoreactive epitope of said MN/CA9 protein.

11. The method of claim 8, wherein said expression is detected by immunohistochemistry.

12. The method of claim 8 wherein said expression is detected by amplification and/or hybridization of mRNA transcripts encoding MN/CA9 protein.